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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,487	07/13/2004	Mitsuaki Oshima	AOY-3983US	9517

23122 7590 06/26/2006

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EXAMINER

TURK, NEIL N

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/501,487	Applicant(s) OSHIMA, MITSUAKI	
	Examiner Neil Turk	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/13/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, and 13, drawn to a biomolecule bead-containing tube.

Group II, claim(s) 7-12, and 14-18, drawn to a reproducer reading out data.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The biomolecule bead-containing tube of group I does not contain the special technical features of group II, which are irradiating the biomolecule bead-containing tube with light and detecting the transmitted or reflected light from at least a mark bead in order to read data.

During a telephone conversation with Lawrence Ashery on June 13th, 2006 a provisional election was made with traverse to prosecute the invention of group I, claims 1-6 and 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-12 and 14-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: The specification should not contain disclosure, which is described in reference to claims in the application. During prosecution of the application, claims may be amended or cancelled, and thus their meaning changed. As such, the specification should be not described through the limitations of claims. Specifically, on page 22 of the specification, reference is made to claim 2, other instances missed by the examiner should be corrected as well. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "identification code", "identification data", and "identification number" in claims 2 are relative terms which renders the claim indefinite. The terms "identification code", "identification data", and "identification number" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "identification code" is a vague term and as such it is unclear as to how the mark beads are arranged. The term "identification data" is a vague and unduly broad term and as such it is unclear what the mark beads indicate. The term "identification number" is a vague term and as such it is unclear what the "identification number" means in relation to the biomolecule-beads containing tube ("for the biomolecule beads-containing tube", claims 5 and 13).

The term "a number" and "larger" in claim 3 is a relative term which renders the claim indefinite. The term "a number" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As claim 3 is recited, it is unclear of the actual relationship of biomolecule beads to mark beads in the two regions. The limitations of "a number of the biomolecule beads is larger than a number of the mark beads" (and vice versa in the 3rd line of the claim) is indefinite as to whether only a set portion of the biomolecule beads needs to be larger than a portion of the marker beads (and vice versa in the 3rd line of the claim), or whether the entire region must maintain this relationship, or whether the term "larger" is not referring to amount, but to size of the respective particles. As a result, dependent claims 4, 6, and 13 carry this same deficiency.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: it is unclear how the recited "first region" and "second region" are structurally defined and related to each other. Without any structural limitations or relationships between the two recited regions, the regions are indistinguishable and no significance can be attributed to the limitations drawn to them. As a result, dependent claims 4, 6, and 13 carry this same deficiency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kambara (6,288,220, corresponding to JP 11-243997). Kambara discloses a DNA probe array. Kambara discloses a probe array, which comprises an array of a plurality of particles (such as beads) having probes respectively fixed thereon and the probes are capable of binding to different target substances such as DNA and proteins (lines 40-45, col. 3). Kambara also discloses that the beads holding the probes are labeled

Art Unit: 1743


with different dyes or fluorophores, respectively, depending on the kinds of probes held by the beads (lines 58-60, col. 3). Kambara also discloses that the particles are arrayed in a predetermined order (lines 65-67). Kambara further discloses that the size and shape of the particles holding the probes corresponds to the kind of probes fixed on the surface of the particles, and that also the particles are labeled with different dyes or fluorophores depending on the kind of probes held by the particles (lines 18-34, col. 4). Kambara also discloses that the small spherical particles (beads) having probes are arrayed in a plurality of transparent capillaries and marker particles are placed between the small spherical particles having different species of probes (lines 22-27, col. 17; lines 1-7, col. 18). Kambara further discloses that the marker particles are placed between the small particles having different kinds of probes and the marker particles are labeled with fluorophores different from the fluorophores labeling the small particles (equivalent to the marker particles being optically distinguishable from the beads) (lines 36-40, col. 6). Kambara also discloses that the positions of the marker particles on the probe array are reference positions for discriminating the species of the probes on the small particles and inserting a marker between the small particles make it easy to know the arraying order of the probes (lines 40-45, col. 6; lines 5-10, col. 10) (equivalent to arranging the mark beads corresponding to an identification code indicating identification data and number).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8919. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT


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